PMS74

INADEQUATE PAIN RELIEF AMONG PATIENTS WITH PRIMARY KNEE OSTEOARTHRITIS - ANALYSIS FROM THE PORTUGUESE SAMPLE OF THE SURVEY OF OSTEOARTHRITIS REAL WORLD THERAPIES (SORT)

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OBJECTIVES: Despite widespread treatments for Osteoarthritis (OA), data on treatment patterns, adequacy of pain relief, and quality of life are limited. The prospective multinational Survey of Osteoarthritis Real World Therapies (SORT) was designed to investigate these aspects. This analysis aims to describe the clinical characteristics and the patient reported outcomes of the Portuguese dataset of SORT baseline. **METHODS:** The statistical analysis included, from January to December of 2011, 192 participants ≥ 50 years or older with primary knee OA from 7 health care centers in Portugal who were receiving oral or topic analgesics. Inadequate Pain Relief (IPR) was defined as a score > 4/10 in item 5 of the *Brief Pain Inventory* (BPI), indicating moderate to severe pain. **RESULTS:** Overall, the median age was 67.0 ± 8.7 years and 77.6% were female. Mean duration of knee OA was 6.3 ± 6.3 years. IPR was reported by 52.0% of the patients. The most prescribed analgesics were NSAIDs (88.1%), alternative therapies, including glucosamine, chondroitin and hyaluronate (44.3%) and paracetamol (28.6%). Patients with IPR scored higher than non-IPR patients in WOMAC – Stiffness (61.0 vs 39.7, p<0.001) and WOMAC – physical function (59.2 vs 39.4, p< 0.001), meaning worse condition. Patients with IPR had worse quality of life related to knee osteoarthritis as measured by the SF-12 questionnaire (fair/poor: 86.9% vs. 72.0%, p<0.001). 62.0% of patients with IPR were dissatisfied or very dissatisfied with the effects of analgesics versus 34.0% of patients with non-IPR (p<0.05). **CONCLUSIONS:** Despite the use of analgesics, over half of the Portuguese patients in SORT reported moderate to severe knee pain. Worse outcomes were also observed in this group regarding other symptoms of knee OA and general quality of life. These findings suggest that if an improvement of pain management in knee OA can be achieved, it may have high impact on patients' lives.

PMS75

QUALITATIVE EQUIVALENCE BETWEEN A PAPER AND ELECTRONIC TABLET VERSION OF THE WOMAC®NRS3.1 AND PATIENT GLOBAL ASSESSMENT

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OBJECTIVES: Prior equivalence work with the WOMAC® scale was published for the VAS scale and older touchscreen computer technology. Additional equivalence evaluation of the WOMAC®NRS3.1 and the Patient Global Assessment (PGA) in a newer tablet with stylus was needed to document suitability of this mode of data collection for these instruments in upcoming clinical trials. **METHODS:** A cross-sectional qualitative study was conducted involving cognitive and usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication for their condition. Interviews were conducted in two waves of 10 participants each, with revisions to the PGA made in between the rounds, which allowed for changes to the electronic version to be evaluated. **RESULTS:** Mean age of the sample (N=20) was 66 years, (range 43-78), 90% over 60 years old; 60% were female; 95% were white; 75% were retired; 70% had completed secondary school or some college, while 30% had completed college or a post-graduate degree. In wave 1, minor issues were found with completing the WOMAC®, mainly with using the stylus to select responses and glare on the screen. There were no issues identified in interpreting the response scale. For the PGA, 50% (5/10) used the wrong recall period (48 hours or longer). The PGA recall period was revised from "at this time" to "over the past 24 hours" and bolded for emphasis. In wave 2, similar issues with glare and stylus response were found, while 80% used the correct recall period on the PGA, with 20% using 48 hours. **CONCLUSIONS:** The study showed excellent qualitative equivalence between the paper and electronic WOMAC® with only minor usability issues. The two wave study design provided the opportunity to detect and make changes to the PGA recall period and formatting that showed improvement in the second wave.

PMS76

LONG-TERM MAINTENANCE OF IMPROVEMENTS IN MULTIPLE FACETS OF PSORIATIC ARTHRITIS WITH CERTOLIZUMAB PEGOL: 96-WEEK PATIENT-REPORTED OUTCOME RESULTS OF THE RAPID-PSA STUDY

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OBJECTIVES: To report the effect of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, on patient-reported outcomes (PROs) in psoriatic arthritis (PsA) over 96 weeks (wks) of the RAPID-PsA trial. **METHODS:** The RAPID-PsA trial (NCT01087788) is double-blind and placebo-controlled to Wk24, dose-blind to Wk48 and open-label to Wk216. Patients had active PsA and had failed ≥1 DMARD. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wk0, Wk2, Wk4) continued on their assigned dose in the dose-blind phase and OLE. Here we present PRO data for the CZP-treated randomized set, including mean change from baseline (CFB) and Minimal Clinically Important Differences (MCIDs). Data were also analysed for CZP-randomized patients with (19.8%) or without (80.2%) prior anti-TNF exposure. Missing data were imputed by LOCF. Correlations between clinical outcomes and PROs were also investigated. **RESULTS:** Of 273 patients randomized to CZP at Wk0, 91% completed Wk24, 87% Wk48, and 80% Wk96. Rapid improvements observed to Wk24 were maintained to Wk96 for pain (Wk24 and Wk96; CFB: -28.5 and -31.3; MCID: 69.2% and 66.3%), fatigue (Wk24 and Wk96; CFB: -2.0 and -2.4; MCID: 64.1% and 60.4%), HAQ-DI (Wk24 and Wk96; CFB: -0.48 and -0.52; MCID: 48.7% and 48.0%), SF-36 PCS (Wk24 and Wk96; CFB: 8.01 and 9.01; MCID: 67.4% and 60.1%), SF-36 MCS (Wk24 and Wk96; CFB: 4.50 and 3.92; MCID: 50.9% and 43.6%), PsAQoL (Wk24 and Wk96; CFB: -3.87 and -4.50), and DLQI (Wk24 and Wk96; CFB: -5.8 and -6.0; MCID: 40.7% and 41.0%). Similar improvements were observed with both dosing regimens and in patients with or without prior anti-TNF exposure. Correlations were observed between improvements in PROs and DAS28 (data not shown). **CONCLUSIONS:** Improvements observed to Wk24 in generic and disease-specific PROs were sustained to Wk96 of the RAPID-PsA trial for both CZP dosing regimens.

PMS77

USABILITY TESTING OF A NOVEL PAIN MEDICATION DIARY ADMINISTERED ELECTRONICALLY

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OBJECTIVES: Pain medication diaries have traditionally been collected via paper due to challenges of patients entering unlimited medications, units, dosages, and administration schedules. This study developed an electronic diary that permits site staff to enter medications that patients are taking, enables the patient to update medication taken and to enter new medications within the reporting period, and reduces the possibility of cheating behaviors during the study. Usability of this electronic diary was evaluated to ensure that patients in a clinical trial setting could successfully update their diaries in real-time to accurately track pain medication intake. **METHODS:** A cross-sectional qualitative study was conducted involving usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication. Interviews were conducted in two waves of 10 participants each, allowing for evaluation of findings and revisions to the eDiary between waves. **RESULTS:** Mean age of the sample (N=20) was 66 years (range 43-78), 90% over 60 years old; 60% were female; 95% were white; 70% completed secondary school or some college. In wave 1, issues were noted with training, selecting responses, exiting to send data, and some wording. For wave 2, the training module was revised to more closely match the diary, wording was revised, and a screen added to facilitate exiting the diary. No issues were noted with training, 4 had trouble selecting responses, and 3 suggested additional instructions on the new screen. No additional changes were made following wave 2. **CONCLUSIONS:** The study showed it is possible to develop an electronic pain medication diary that allows patients to update their medications during a study. Extensive training was critical to the usability of the electronic version. The two wave study design provided the opportunity to detect and make changes to the eDiary with marked improvement in wave 2.

PMS78

QUALITY OF LIFE IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS IN CLINICAL PRACTICE IN SWEDEN: BASELINE RESULTS FROM A LONGITUDINAL STUDY

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OBJECTIVES: Spondyloarthritis (SpA) is a group of diseases that share common clinical, radiographic and genetic features. Axial SpA is one major subgroup including patients with radiographic (rad-axSpA) and non-radiographic axSpA (nr-axSpA). There has been limited research on axSpA patients in clinical practice and the impact of the disease on patient's health-related quality of life (HrQoL). The aim of this study was to characterize patients with axSpA in clinical practice and to investigate similarities/differences between rad-axSpA and nr-axSpA with respect to their HrQoL. **METHODS:** This is a longitudinal, multi-center cohort study where patients were consecutively recruited from Swedish clinical practice and followed for 3 months. At baseline, the rheumatologists registered information on disease history, extra articular manifestations and treatments. The patients answered online questionnaires capturing patient demographics, disease activity, function and HrQoL. HrQoL was measured using the EQ-5D and the Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL). While higher scores in the EQ-5D indicate better HrQoL, the opposite is true for the ASQoL. **RESULTS:** 251 patients were included of whom 197 (78%) were classified as axial SpA. Of those, 125 (63%) were classified as rad-axSpA and 72 (37%) as nr-axSpA according to the ASAS axSpA criteria. There were more women in the nr-axSpA group (50%) compared with the rad-axSpA group (38%). The nr-axSpA patients had a shorter time between symptom onset and diagnosis than the rad-axSpA patients (6.7 vs. 9.0 years) and a significantly higher disease activity (BASDAI=4.1 vs 2.7, p<0.001). Mean EQ-5D score at baseline was 0.66 for rad-axSpA and 0.61 for nr-axSpA, lower than the Swedish general population (0.84). ASQoL scores was significantly higher in the nr-axSpA group (8.8 vs 6.4, p=0.016). **CONCLUSIONS:** HRQoL is poorer in axial SpA patients compared to the general population and patients with nr-axSpA reported a higher impact on HRQoL than patients with rad-axSpA.

PMS79

FUNCTIONAL STATUS, QUALITY OF LIFE AND WORK DISABILITY FOR PATIENTS WITH RHEUMATIC DISEASES IN GREECE

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OBJECTIVES: Rheumatic diseases (RD) have been associated with functional and work-related disability due to the deliberating and progressive nature of these diseases and have many deleterious consequences on patients' life. *The aim of the*

present study was to measure the functional status and quality of life in RD patients receiving the biologic agent golimumab in Greece **METHODS:** A descriptive study was conducted estimating the annual Quality-of-Life (QoL) improvement for 148 patients diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PS) and ankylosing spondylitis (AS). QoL was estimated with standardized questionnaires such as EQ-5D and HAQ questionnaire. In addition, twenty specific parameters including "general health", "severity of pain", "productivity level" etcetera wereassessed on 10-point Likert scale. Data was collected by doctors across the country at 3 month intervals (4 waves of questionnaires during the year). **RESULTS:** Patients with RA reported improved QoL by 14%, followed by 0.67 decrease of average HAQ score. They also reported a 7.5 hours gain of working hours and an overall 14% gain in productivity per week. Patients with AS were estimated to present 30% improvement in general health condition according to their doctors with similar self-reported estimations. Additionally, their QoL was improved by 17%. Similarly, patients with PS estimated their QoL improved by 17% with a 6hr/week gain in working hours otherwise missed, while the average HAQ score fell by 0.71 Findings are in accordance with similar published studies all contributing to the general assumption that patients receiving biological agents experience greater QoL improvement compared to conservative treatment options. **CONCLUSIONS:** Statistical analysis revealed significant improvement of functional status, quality of life, productivity gains and decrease of disease activity for those receiving Golimumab in Greece for all three disease groups. Amongst limitations, both number of the study group and follow-up period should be taken into consideration.

PMS80

QUALITY OF LIFE IN PATIENTS WITH CHRONIC LUMBOSCIATIC SYNDROME IN THE SLOVAK REPUBLIC

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OBJECTIVES: The current prevalence of Chronic Lumbosciatic Syndrome (CLSS) in Slovakia ranges in about 170000 cases. The CLSS has a great impact on quality of life (QoL) and the ability to work too. Till now in Slovakia was not realised the study like this. **METHODS:** 86 patients with CLSS were studied. The "hospital" and the "out-patients clinic" group had 43 vs 43 patients. The average age was 50.36 vs 51.79 y., weight – 61.04 vs 77.95 kg, duration of illness – 5.3 vs 5.0 years, symptoms of illness before diagnosis – 2.27 vs 2.16 years. QoL and the ability to work was evaluated on the numeric scale from 0 to 10 (0 for the worst, 10 for the best) by patients themselves. **RESULTS:** The "hospital" and the "out-patients clinic" group had these results: the average of hospitalisation – 1.51 vs 1.44 times, incapacity to work – 3.06 vs 2.90 months. QoL in the time of good health was 8.2 vs 8.04, in the time of diagnosis – 5.86 vs 6.74, and in the current time – 4.58 vs 3.95. The work ability (WA) had these results: WA in time of good health was 8.97 vs 9.04 in the time of diagnosis – 8.16 vs 8.13, and in the current time – 3.83 vs 3.83. The impact of the treatment on the QoL was 5.37 vs 6.06 and on the patients families QoL it was 6.16 vs 6.13. The willingness to pay for the perfect cure was 477.90 € vs 524.41 € per month (the average salary in Slovakia in 2013 was 824 €). **CONCLUSIONS:** CLSS has a great impact on QoL and on the WA too. There was not statistical difference between both "hospital and out-patient clinic" patients in the QoL and WA. Early diagnosis is important to effective treatment.

PMS81

REASONS FOR TREATMENT DISCONTINUATION OF BIOLOGICS – DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE

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OBJECTIVES: For patients with rheumatoid arthritis (RA) and inadequate response to traditional therapy, treatment with biologics is recommended to reduce disease progression and improve HRQol. Nevertheless, up to 30% of patients stop treatment on their own initiative. Aim of the study is to develop and validate an instrument to assess reasons for treatment discontinuation of biologics in patients with RA. **METHODS:** We conducted expert interviews with rheumatologists (n=5) to develop a questioning route, which was used in 2 focus groups with a total of 15 RA patients who dropped out therapy (phase 1). Based on these results a draft questionnaire was developed and pre-tested (phase 2; n=6), resulting in the pilot questionnaire. In the validation phase (phase 3) the questionnaire is completed by approx. 200 patients, with an interim analysis planned after recruitment of half the sample size. Quantitative data analyses will focus on psychometric properties: missing data, floor/ceiling effects, factorial validity, distribution of properties. Patients are recruited at 40 German office based rheumatologists, with 5 patients per center. **RESULTS:** The final questionnaire consists of 82 items covering sociodemographic aspects, HRQoL, history of treatment and disease, treatment information, expectations and satisfaction and "reasons for discontinuation". Piloting showed that HRQoL, treatment and working-life aspects have impact on treatment discontinuation. Particularly, information about treatment options, patient-doctor relationship and financial burden were addressed. The questionnaire has proven to be feasible in field-test. Validation phase is currently ongoing; results from the interim analysis will be presented. **CONCLUSIONS:** Interviews with experts and patients demonstrated that treatment discontinuation is triggered by multiple reasons. A targeted developed questionnaire is necessary to identify latent reasons for treatment discontinuation. Furthermore, an "easy-to-use" questionnaire could be used in daily routine to identify patients likely to withdraw treatment and need special patient adherence programs.This research was funded by Pfizer GmbH.

PMS82

ASSESSING WILLIGNESS TO PAY AMONG PSORIASIS AND PSORIATIC ARTHRITIS PATIENTS

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OBJECTIVES: It is estimated that 30% of psoriasis (PSO) patients also develops psoriatic arthritis (PSA). This potential disease evolution brings along new symptoms such as swollen and painful joints and mobility problems. Since both diseases are potentially degenerative, the aim of this study was to measure which group of patients (PSO or PSA) is willing to pay most out of pocket to avoid their health related quality of life (HRQoL) to worsen. **METHODS:** 395 US patients diagnosed with either psoriasis (n=151) or psoriatic arthritis (n=247) completed a questionnaire as part of a broader survey of treatment of PSO/PSA. The questionnaire included the EQ-5D-5L instrument and accompanying VAS. Patients were additionally asked to indicate by reference to the EQ-5D VAS scale the amount of money per month they would be willing to pay for treatments that would prevent a decline in HRQoL by 10 points. Price sensitivity curves were created by means of linear regression analysis that predict the proportion of patients willing to pay a certain amount of $ out of pocket per month. **RESULTS:** For both PSO ($R^2 = 0,82$) and PSA ($R^2 = 0,86$) monthly cost out of pocket (x-variable) was a good predictor of the proportion of patients that is willing to pay a certain amount out of pocket per month (y-variable). Regression models look as follows. For PSO: $y = 0,77e^{-0,005x}$ for PSA: $y = 0,86e^{-0,007x}$. To give a specific example 42% of the PSA patients is willing to pay $100 per month out of pocket whereas this is 47% among PSO patients. **CONCLUSIONS:** PSO patients are prepared to pay more out of pocket on a monthly basis to avoid their HRQoL to worsen than PSA patients. Further research is required to understand what drives this difference.

PMS83

SUSTAINED IMPROVEMENTS IN WORKPLACE AND HOUSEHOLD PRODUCTIVITY AND SOCIAL PARTICIPATION WITH CERTOLIZUMAB PEGOL OVER 96 WEEKS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS, INCLUDING ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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OBJECTIVES: To report the long-term effect of certolizumab pegol (CZP) on workplace and household productivity up to 96 weeks (wks) in patients with axial spondyloarthritis (axSpA), including ankylosing spondylitis (AS, meeting modified New York criteria) and non-radiographic axSpA (nr-axSpA). **METHODS:** The ongoing RAPID-axSpA trial (NCT01087762), is double-blind and PBO-controlled to Wk24, dose-blind to Wk48 and open-label to Wk204. Patients had active axSpA, according to ASAS criteria, including AS and nr-axSpA patients. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose [LD] at Wks 0, 2, 4) continued on their assigned dose in the OLE; PBO patients entering dose-blind phase were re-randomized to CZP LD followed by CZP 200mg Q2W or CZP 400mg Q4W after Wk24 or, for non-responders, after Wk16. The validated arthritis-specific Work Productivity Survey (WPS; administered Q4W) assessed the impact of axSpA on workplace and household productivity. WPS responses (LOCF imputation) in patients originally randomized to CZP are summarized descriptively over 96 wks. **RESULTS:** 325 patients were randomized, of whom 218 received CZP (200mg Q2W or 400mg Q4W) from Wk0. Of patients randomized to CZP at baseline (BL), 93% completed Wk24, 88% Wk48 and 80% Wk96. At BL, 72% of CZP patients were employed outside of the home. Employed CZP patients reported reductions in workplace absenteeism and presenteeism to Wk24, with continued improvements to Wk96 (BL: mean 1.8 days missed/month, mean 5.2 days with reduced productivity/month vs Wk96: mean 0.6 days missed/month, mean 1.4 days with reduced productivity/month). CZP patients also reported continued improvements in household productivity and social participation to Wk96 in both dose regimens, and similar improvements were observed in AS and nr-axSpA. **CONCLUSIONS:** The initial improvements with CZP in workplace and household productivity and increased participation in social/leisure activities were continued to Wk96 in axSpA, AS and nr-axSpA patients.

PMS84

SUSTAINED IMPROVEMENTS IN WORKPLACE AND HOUSEHOLD PRODUCTIVITY AND SOCIAL PARTICIPATION WITH CERTOLIZUMAB PEGOL OVER 96 WEEKS IN PATIENTS WITH PSORIATIC ARTHRITIS

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OBJECTIVES: To examine the long-term effect of certolizumab pegol (CZP) on workplace and household productivity up to 96 weeks (wks) in patients with active psoriatic arthritis (PsA). **METHODS:** The ongoing RAPID-PsA trial (NCT01087788) is double-blind and PBO-controlled to Wk24, dose-blind to Wk48 and open-label to Wk216. Patients had active PsA and had failed ≥1 DMARD. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose [LD] at Wks 0, 2, 4) continued on their assigned dose in the OLE; PBO patients entering dose-blind phase were re-randomized to CZP LD followed by CZP 200mg Q2W or 400mg Q4W after Wk24 or, for non-responders, Wk16. The validated arthritis-specific Work Productivity Survey (WPS) administered Q4W from baseline (BL), assessed the impact of PsA on workplace and household productivity in the randomized set. WPS responses (LOCF imputation) in patients originally randomized to CZP groups are summarized descriptively over 96 wks. **RESULTS:** 409 patients were randomized, of whom 273 received CZP 200mg Q2W or CZP 400mg Q4W. Of patients randomized to CZP, 91% completed Wk24, 87% Wk48 and 80% Wk96. In employed patients in both CZP groups (60.8% of all CZP patients at BL), decreases in absenteeism and presenteeism to Wk24 were continued up to Wk96 (BL: mean 2.0 and 1.6 days missed/month in the CZP 200mg Q2W and 400mg Q4W groups, respectively; mean 5.2 and 5.1 days with reduced productivity/month vs Wk96: mean 0.3 and 0.4 days missed/month; mean 0.7 and 1.5 days with reduced productivity/month). Improvements in household productivity and social participation reported in both CZP groups over 24 wks were also maintained to Wk96. **CONCLUSIONS:** The initial improvements